REMARKS

Claim Amendments

Claim 7 is canceled. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the inventions of the canceled claims. Applicants do not hereby abandon or waive any rights in the inventions of the canceled claim.

Claims 1 and 10 are amended to cancel sub-parts iii and iv. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the inventions of the canceled subject matter. Applicants do not hereby abandon or waive any rights in the inventions of the canceled subject matter.

Entry of the amendments is respectfully requested.

Priority

The Examiner states that the "instant application has been granted the benefit date, 18 September 2001, from the application 60/322,993" (Office Action, page 2). However, as already noted in Applicants' response filed on January 19, 2007, and acknowledged in the Office Communication dated March 26, 2007, the instant application should be granted the earlier benefit date of 22 August 2001. Applicants have properly claimed their right of priority in the "Related Applications" paragraph of the specification at page 1, lines 2-7. Since the earliest filed application (U.S. Application No. 60/314,046), which supports the instant application, has a filing date of August 22, 2001, Applicants should be entitled to the benefit of this date. Reconsideration is respectfully requested.

Rejection of Claim 7 Under 35 U.S.C. §112, First Paragraph

Claim 7 stands rejected by the Examiner under 35 U.S.C. §112, first paragraph, Written Description requirement (Office Action, page 3). Specifically, the Examiner states that "claiming sequences based on functionality is not sufficient to demonstrate support for a genus of indeterminate sequences" (Office Action, page 3). The Examiner concludes that "a skilled artisan would not recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed" (Office Action, page 4).

Applicants respectfully disagree. However, to expedite prosecution, Applicants have canceled Claim 7.

Rejection of Claim 7 Under 35 U.S.C. §112, First Paragraph

Claim 7 stands rejected by the Examiner under 35 U.S.C. §112, first paragraph, Enablement requirement (Office Action, page 4). Specifically, the Examiner asserts that "the applicant has not overcome the uncertainty encountered when isolating nucleic acids by hybridization methods and overcome the lack of guidance and working examples" (Office Action, page 5).

Applicants respectfully disagree. However, as noted above, to expedite prosecution, Applicants have canceled Claim 7.

Rejection of Claims 1-2 and 4-5 Under 35 U.S.C. §102(b)

Claims 1-2 and 4-5 stand rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Lamerdin et al. (Genbank Accession NO. AD000864, 22 March 1997) (Office Action, page 9). The Examiner acknowledges that the Lamerdin *et al.* sequence does not teach an isolated nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1 or the complement thereof (Office Action, page 11). However, the Examiner reasserts that with respect to Claims 4 and 5, "the sequence taught by Lamerdin et al. teaches an isolated nucleic acid molecule consisting of a nucleic acid sequence selected from...a nucleic acid that encodes SEQ ID NO: 2" (Office Action, page 10). The Examiner further asserts that "IkBNS (SEQ ID NO:2) is encoded by SEQ ID NO:1 and IkBNS has been demonstrated to be a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells. Therefore, Lamerdin et al. teaches an isolated nucleic acid sequence that ***inherently*** reduces NF-kB sensitive reporter activity in Cos cells" (Office Action, page 10, emphasis added). The Examiner also asserts that "the reverse complement of a GenBank DNA sequence is ***inherent*** in the sequence submitted" (Office Action, page 11, emphasis added).

Applicants respectfully disagree. As a preliminary matter, Applicants note that Claim 1, as amended, is directed to subject matter which the Examiner acknowledged is novel in view of Lamerdin *et al* (Office Action, page 11).

With respect to the rejection against Claims 4 and 5, Applicants contend that Lamerdin *et al.* does not teach an isolated nucleic acid sequence that ***inherently*** reduces NF-kB sensitive reporter activity in Cos cells, nor that a reverse complement of a GenBank DNA sequence is ***inherent*** in the sequence submitted. As pointed out before, Lamerdin *et al.*, discloses a 39,146 base, single-stranded DNA sequence. This sequence does not consist of or comprise an isolated nucleic acid sequence that encodes SEQ ID NO: 2 because the Lamerdin *et al.* sequence ***needs to be manipulated*** into the reverse sequence and converted to a complementary sequence and correctly translated in-frame before it comprises a nucleic acid sequence that encodes SEQ ID NO: 2. There is no teaching in Lamerdin *et al.* of performing any and all of these steps. Furthermore, at the time this application was filed, a person of ordinary skill in the art did not routinely perform these manipulations, thus, it would not be inherent in the Lamerdin *et al.* disclosure. In addition, there is no teaching in Lamerdin *et al.* that the encoded polypeptide would reduce NF-$_K$B-sensitive reporter activity in Cos cells. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-6 Under 35 U.S.C. § 103(a)

Claims 1-6 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being obvious in view of Lamerdin *et al.* Specifically, the Examiner asserts that "[a]s described above, in the discussion of Lamerdin et al. under the 35 USC 102 section, Lamerdin teaches the limitations of claims 1-2 and 4-5. Since the Lamerdin sequence meets the sequence limitations of claims 1-2 and 4-5 and ***intrinsically*** contains sequences that encode a polypepetide that reduces NF-kB sensitive reporter activity in Cos cells, the examiner maintains that these teachings are obvious over these claims" (Office Action, page 12, emphasis added).

Applicants respectfully disagree. Claim 1, as amended, is directed to subject matter which the Examiner acknowledges as being novel (Office Action, page 11). Claim 4 is generally directed to an isolated acid molecule which encodes a polypeptide that reduces NF-$_K$B-sensitive reporter activity in Cos cells.

For the following reasons the Examiner has failed to state a *prime facie* case.

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would

> have been obvious. The Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also KSR, 550 U.S. at ___ , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).
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The Examiner's reasoning appears to fit best under the rational discuss under (G).

> *(G) Some Teaching, Suggestion, or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention* (Emphasis added)
>
> To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:
>
> (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
> (2) a finding that there was reasonable expectation of success; and
> (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.
>
> The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.
>
> *Id.*

There is no teaching or suggestion of a polypeptide that reduces NF-$_K$B-sensitive reporter activity in Cos cells by Lamerdin *et al.* Nor is a polypeptide with this activity intrinsic in the Lamerdin *et al.* sequence because the Lamerdin *et al.* sequence ***needs to be manipulated*** into the reverse sequence and converted to a complementary sequence and correctly translated in-frame before it comprises a nucleic acid sequence that encodes a polypeptide that reduces NF-$_K$B-sensitive reporter activity in Cos cells. In addition, as noted above, at the time this application was filed, a person of ordinary skill in the art did not routinely perform these manipulations. Thus, a person of ordinary skill in the art would not even be motivated to perform such manipulations. There is no intrinsic teaching or suggestion in the Lamerdin *et al.* disclosure to perform such manipulations. Certainly there is no explicit teaching or suggestion by Lamerdin *et al.* to perform such manipulations. Thus, Claims 1-6 cannot be obvious in view of Lamerdin *et al.* Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections of Claims 10-12 Under 35 U.S.C. §103(a)

Claims 10-12 stand rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Lamerdin et al. (GenBank Accession No. AD0008624 22 March 1997) in view of Liu et al. (Current Biology, 19 November 1998, 8:1300-1309) (Office Action, pages 13-14). Specifically, the Examiner reasserts that the Lamerdin et al. sequence "does indeed satisfy the limitations of claims 1 and 4. Essentially, the vectors of claims 10-11 comprise the nucleic acids of claims 1 or 4. The cell of claim 12 comprises the vector of claim 11. Because there is sufficient motivation to combine the vectors and cells of Liu et al. with the Lamerdin sequence and the examiner holds that the Lamerdin sequence meets the limitations of the isolated nucleic acids sequences described in claim 10, the rejection of claims 10-12 under 35 USC 103(a) is maintained" (Office Action, page 14).

Applicants respectfully disagree. Claim 10, and thus, Claims 11 and 12 which are dependent thereon, as amended, is directed to a vector or plasmid comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1, the complement of SEQ ID NO: 1, and a nucleic acid sequence that encodes SEQ ID NO: 2. As noted by the Examiner above, the Lamerdin et al. sequence does not teach an isolated nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1 or the complement thereof. Furthermore, Lamerdin *et al.* does not teach or suggest a vector or plasmid or plasmid comprising a nucleic acid sequence

that encodes SEQ ID NO: 2. In particular, Lamerdin *et al.* does not teach or suggest manipulating the Lamerdin *et al.* sequence into a reverse ***and*** complementary sequence, ***and*** in-frame such that the translation product would encode SEQ ID NO: 2. The teachings of Liu *et al.* fail to remedy the deficiencies of Lamerdin *et al.* Thus, Claims 10-12 cannot be obvious in view of Lamerdin *et al.* Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-3, 7 and 10-12 Under 35 U.S.C. §112, First Paragraph

Claims 1-3, 7 and 10-12 are rejected by the Examiner under 35 U.S.C. §112, first paragraph, as "failing to comply with the written description requirement" (Office Action, page 14). Specifically, the Examiner states that "Claims 1, 7, and 10 are broadly drawn, such that they apply to a genus of isolated nucleic acids that are complements of SEQ ID NO:1 (or portions thereof) and encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells" (Office Action, page 15).

Applicants respectfully disagree. As a preliminary note, as noted above, Applicants have canceled Claim 7. Furthermore, Applicants have amended Claims 1 and 10. As amended, Claims 1 and 10 are not "broadly drawn, such that they apply to a genus of isolated nucleic acids that are complements of SEQ ID NO:1 (or portions thereof) and encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells" thereby rendering the present rejection moot. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claim 39 Under 35 U.S.C. §102(b)

Claim 39 is rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Lamerdin *et al.* (Genbank Accession NO. AD000864, 22 March 1997) (Office Action, page 17). Specifically, the Examiner asserts that the "Lamerdin et al. sequence teaches all of the 15000 bases of SEQ ID NO:1. . . . The claim language of claim 39 contains closed language ('consisting of') followed by open language ('encodes'). Many molecules can encode SEQ ID NO:2." (Office Action, page 17). The Examiner further asserts that "the sequences that are taught by Lamerdin which meet the sequence limitations of claim 39 ***inherently*** encode a polypeptide that reduces NF-kB sensitive reporter activity in Cos cells" (Office Action, page 18, emphasis added).

Applicants respectfully disagree. Lamerdin *et al.* discloses a 39,146 base, single-stranded DNA sequence. This sequence does not consist of or comprise an isolated nucleic acid sequence that encodes SEQ ID NO: 2 because the Lamerdin *et al.* sequence ***needs to be manipulated*** into the reverse sequence and converted to a complementary sequence and correctly translated in-frame before it ***comprises*** a nucleic acid sequence that encodes SEQ ID NO: 2. There is no teaching in Lamerdin *et al.* of performing any and all of these steps. Furthermore, at the time this application was filed, a person of ordinary skill in the art did not routinely perform these manipulations, thus, it would not be inherent in the Lamerdin *et al.* disclosure. Still further, there is no teaching in Lamerdin *et al.* of a nucleic acid molecule ***consisting*** of a nucleic acid sequence that encodes SEQ ID NO: 2. In addition, there is no teaching in Lamerdin *et al.* that an encoded polypeptide produced by reversing the Lamerdin *et al.* sequence ***and*** producing the complementary sequence of the reversed sequence ***and*** translating the resulting sequence in-frame would result in a polypeptide that reduces NF-$_K$B-sensitive reporter activity in Cos cells.

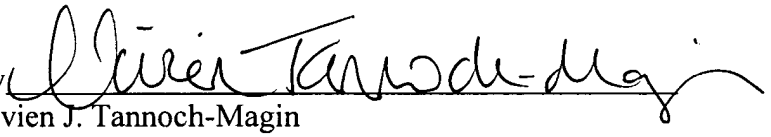
Since Lamerdin *et al.* does not teach each and every element of the claimed invention, Claim 39 is not anticipated. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 
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Date: January 4, 2008